

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TWINSTRAND BIOSCIENCES, INC. &)
UNIVERSITY OF WASHINGTON,)
)
Plaintiffs and)
Counterclaim Defendants,)
)
v.) C.A. No. 21-1126-LPS
)
GUARDANT HEALTH, INC.,)
)
Defendant and)
Counterclaim Plaintiff.)
)
)

**PLAINTIFFS' OPENING BRIEF IN SUPPORT OF THEIR PARTIAL MOTION TO
DISMISS GUARDANT HEALTH'S COUNTERCLAIMS
(COUNTS V-VIII) AND RELATED AFFIRMATIVE DEFENSES**

Dated: February 11, 2022

YOUNG CONAWAY STARGATT
& TAYLOR, LLP

Of Counsel:
Byron Pickard
R. Wilson Powers III, Ph.D.
Chandrika Vira
Anna G. Phillips
Matthew M. Zuziak
STERNE, KESSLER, GOLDSTEIN
& FOX, P.L.L.C.
1100 New York Avenue, NW
Washington, DC 20005
(202) 371-2600

Adam W. Poff (No. 3990)
Samantha G. Wilson (No. 5816)
Rodney Square
1000 North King Street
Wilmington, DE 19801
(302) 571-6600
apoff@ycst.com
swilson@ycst.com

*Attorneys for Plaintiffs TwinStrand
Biosciences, Inc. and University of
Washington*

TABLE OF CONTENTS

I.	NATURE AND STAGE OF PROCEEDINGS	1
II.	SUMMARY OF ARGUMENT	1
III.	BACKGROUND	3
IV.	ARGUMENT	5
A.	The Court should dismiss Guardant's inequitable-conduct challenges because Guardant has not pled sufficient, particularized facts to support them.....	6
1.	Guardant pleads almost no facts beyond Plaintiffs' alleged failure to notify the Patent Office of its alleged claim copying.	8
2.	Guardant does not plead adequate facts to show any individual specifically intended to deceive the Patent Office.....	10
3.	Guardant fails to adequately plead materiality.	13
B.	The Court should dismiss Guardant's inventorship challenges.....	15
1.	Guardant has not alleged facts sufficient to show the '699 and '951 patents improperly name inventors.....	16
2.	Pre-AIA Section 135(b) does not provide a cause of action.....	17
C.	If Counts V–VIII are dismissed, UW should be dismissed as a Counterclaim Defendant	18
V.	CONCLUSION.....	18

TABLE OF AUTHORITIES

	Page(s)
Cases	
<i>Agilent Tech., Inc. v. Affymetrix, Inc.</i> , 567 F.3d 1366 (Fed. Cir. 2009).....	17
<i>Ashcroft v. Iqbal</i> , 556 U.S. 662 (2009).....	5, 17
<i>Bayer CropScience</i> , C.A. No. 10-1045, 2011 WL 6934557 (D. Del. Dec. 30, 2011)	8
<i>Bell Atlantic Corp. v. Twombly</i> , 550 U.S. 544 (2007).....	5, 13, 17
<i>Bot M8 LLC v. Sony Corp. of America</i> , 4 F.4th 1342 (Fed. Cir. 2021)	13, 14
<i>Burlington Coat Factory Sec. Litig.</i> , 114 F.3d 1410 (3d Cir. 1997).....	6
<i>Chiron Corp. v. Genentech, Inc.</i> , 268 F. Supp. 2d 1148 (E.D. Cal. 2002).....	18
<i>Cumberland Pharm. Inc. v. Mylan Institutional LLC</i> , 846 F.3d. 1213 (Fed. Cir. 2017).....	16
<i>Evonik Degussa GmbH v. Materia Inc.</i> , C.A. No. 09-cv-636, 2012 WL 4503771 (D. Del. Oct. 1, 2012)	6, 7, 13
<i>Exergen Corp. v. Wal-Mart Stores, Inc.</i> , 575 F.3d 1312 (Fed. Cir. 2009).....	<i>passim</i>
<i>FMC Corp. v. Manitowoc Co., Inc.</i> , 835 F.2d 1411 (Fed. Cir. 1987).....	6
<i>Gemstar-TV Guide Int'l, Inc. Int'l Trade Comm'n</i> , 383 F.3d 1352 (Fed. Cir. 2004).....	16
<i>Guidotti v. Legal Helpers Debt Resol., L.L.C.</i> , 716 F.3d 764 (3d Cir. 2013).....	3
<i>Helsinn Healthcare S.A. v. Dr. Reddy's Lab. Ltd.</i> , 387 F. Supp. 3d 439 (D.N.J. 2016)	4

<i>Invista North America S.a.r.l. v. M&G USA Corp.</i> , C.A. No. 11-1007-SLR-CJB, 2013 WL 12304544 (D. Del. May 3, 2013)	12
<i>EMC Corp. v. Zerto, Inc.</i> , C.A. No. 12-956-GMS, 2014 WL 3809365 (D. Del. July 31, 2014)	17
<i>Johns Hopkins Univ. v. 454 Life Sciences Corp.</i> , 123 F. Supp. 3d 563 (D. Del. 2015)	17
<i>Mayer v. Belichick</i> , 605 F.3d 223 (3d Cir. 2010)	3
<i>Molins PLC v. Textron, Inc.</i> , 48 F.3d 1172 (Fed. Cir. 1995)	7
<i>Outside the Box Innovations, LLC v. Travel Caddy, Inc.</i> , 695 F.3d 1285 (Fed. Cir. 2012)	7
<i>Pinnavaia on behalf of Pinnavaia v. Celotex Asbestos Settlement Trust</i> , 271 F. Supp. 3d 705 (D. Del. 2017)	3
<i>Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V.</i> , 528 F.3d 1365 (Fed. Cir. 2008)	14
<i>Senju Pharm. Co., Ltd. v. Apotex, Inc.</i> , 921 F. Supp. 2d 297 (D. Del. 2013)	8
<i>In re Spina</i> , 975 F.2d 854 (Fed. Cir. 1992)	17
<i>Storer v. Clark</i> , 860 F.3d 1340 (Fed. Cir. 2017)	4
<i>Therasense, Inc. v. Becton, Dickinson and Co.</i> , 649 F.3d 1276 (Fed. Cir. 2011) (<i>en banc</i>)	<i>passim</i>
<i>UUSI, LLC v. United States</i> , 133 Fed. Cl. 263 (Fed. Cl. 2017)	7
<i>Xilinx, Inc. v. Invention Inv. Fund I LP</i> , C.A. No. 11-0671 SI, 2011 WL 3206686 (N.D. Cal. July 27, 2011)	15
Statutes	
35 U.S.C. § 100(i)(1)(A)	4
35 U.S.C. § 112	17
35 U.S.C. § 116	15

35 U.S.C. § 135.....1, 17, 18

35 U.S.C. § 282.....18

Other Authorities

37 C.F.R. § 1.607(6)(c).....17

37 C.F.R. § 1.56(b).....7

Fed. R. Civ. P. 9(b).....*passim*

Fed. R. Civ. P. 12(b)(6).....1

Fed. R. Civ. P. 12(f).....1

MPEP § 2306.0117

I. NATURE AND STAGE OF PROCEEDINGS

On August 3, 2021, Plaintiffs TwinStrand Biosciences, Inc. and University of Washington (“UW”) (collectively, “Plaintiffs”) filed suit against Guardant Health, Inc. for infringement of four UW patents that are exclusively licensed to TwinStrand. D.I. 1. Guardant answered on October 1, 2021, asserting no counterclaims. D.I. 10. Over three months later, Guardant filed an amended answer and counterclaims. D.I. 30. Plaintiffs now move to dismiss Guardant’s Counterclaim Counts V–VIII and to strike its affirmative defenses that correspond to these counts under Fed. R. Civ. P. 12(b)(6) and (f).

II. SUMMARY OF ARGUMENT

Guardant’s Amended Answer and Counterclaims include two counterclaims (Counts V & VI) that challenge whether the inventors are properly named in Plaintiffs’ asserted U.S. Patents Nos. 10,689,699 and 10,752,951, and two counterclaims (Counts VII & VIII) that allege those two patents are unenforceable for inequitable conduct. In addition, Guardant has raised three affirmative defenses that correspond to these counterclaims: (i) the Fourth Affirmative Defense contends that all four UW patents are invalid for failure to name the correct inventors, (ii) the Eighth Affirmative Defense raises inequitable-conduct defenses¹; and (iii) the Twelfth Affirmative Defense contends that the ’699 patent is invalid for failing to comply with 35 U.S.C. § 135(b). D.I. 30 at 19–21. All four counterclaims and the related affirmative defenses should be dismissed. UW should also be dismissed as a Counterclaim-Defendant because Counts V–VIII

¹ Guardant’s Eighth Affirmative Defense is styled “Unclean Hands” but appears to cover (if not be co-extensive with) Guardant’s inequitable-conduct counterclaims, insofar as they seek relief for Plaintiffs’ alleged “acts, conduct, and omissions...before, during, and after prosecution of the Asserted Patent[sic].” D.I. 30 at 20. It is not possible to say so with certainty, however, because Guardant has refused to provide any interrogatory response stating the factual basis for this affirmative defense.

are the only counterclaims that implicate UW.

These counterclaims and defenses are all premised on the core allegation that Plaintiffs copied patent claims from Guardant’s patent filings into the applications that issued as the ’699 and ’951 patents—without notifying the Patent Office that they had done so. Beyond that, Guardant adorns its counterclaims with little more than quotations of law and conclusory assertions of the ultimate legal conclusions.

Guardant’s factually threadbare allegations do not adequately plead inequitable-conduct claims because such allegations must be made with particularity under Fed. R. Civ. P. 9(b). In particular, Guardant fails to plead facts plausibly showing that anyone specifically intended to deceive the Patent Office or that Plaintiffs’ alleged omissions were but-for material as to patentability.

Likewise, Guardant’s counterclaims challenging inventorship fail because they do not allege basic facts that anyone conceived of the ’699 and ’951 patents’ inventions before the named inventors, or even that the named inventors failed to conceive of the inventions in those patents in the first place. This omission is significant because alleging merely that Plaintiffs copied claims, without more, does not suggest any issue of improper inventorship.

These gaps in Guardant’s pleading are compounded by Guardant’s inclusion of demonstrably false and misleading allegations. Most glaringly, Guardant alleges that certain claims appearing in the application to the ’699 patent “were *exact copies* of claims...from Guardant’s ’822 patent.” D.I. 30, ¶ 250 (emphasis added). But that is plainly false when one compares the claims in the application to the ’699 patent to those present in the ’822 patent—as

the Court may do under Rule 12(b)(6).^{2,3} Section IV.A.2 at 12 *infra*. Elsewhere, Guardant alleges that Plaintiffs copied claims in another patent application (referred to below as the “’305 application”), but, unlike the applications to the ’699 and ’951 patents, Plaintiffs notified the Patent Office of this. Guardant then alleges “no patent issued from [that] Application,” for the apparent purpose of suggesting that Plaintiffs hid their alleged acts of copying here to avoid a similar fate for those applications. *Id.*, ¶ 268. But Guardant’s allegation is misleading. When it filed its counterclaims, the Patent Office had issued a Notice of Allowance for the ’305 application⁴, which has since issued as U.S. Patent No. 11,242,562—without a single amendment to the claims Plaintiffs copied.

III. BACKGROUND

All four TwinStrand and UW asserted patents cover groundbreaking sequencing methods, including duplex-sequencing methods that allow, for the first time, reliable, early, non-invasive cancer detection and post-treatment cancer monitoring in patients simply by analyzing blood plasma. These patented inventions were conceived by the inventors through their work at UW. D.I. 1. The inventors ultimately founded TwinStrand to make their technology available to researchers and clinicians.

² As discussed below, if the claims are not exact copies, then there is no reason to infer that anyone specifically intended to copy anything, let alone intended to deceive the Office in so doing.

³ The court may consider Plaintiffs’ exhibits attached to its motion to dismiss without converting it to a motion for summary judgment because these exhibits are matters of public record and Guardant relies on these patents and their prosecution histories for the basis of its counterclaims. *See, e.g., Guidotti v. Legal Helpers Debt Resol., L.L.C.*, 716 F.3d 764, 772 (3d Cir. 2013) (quoting *Mayer v. Belichick*, 605 F.3d 223, 230 (3d Cir. 2010)); *Pinnavaia on behalf of Pinnavaia v. Celotex Asbestos Settlement Trust*, 271 F. Supp. 3d 705, 708–09 (D. Del. 2017).

⁴ Because Guardant referenced this application in its pleading, the Court may consider it on a Rule 12(b)(6) motion. *See, e.g., Guidotti*, 716 F.3d at 772 (3d Cir. 2013); *Pinnavaia*, 271 F. Supp. 3d at 708–09.

The Guardian counterclaims and defenses that are relevant to this motion attack the validity and enforceability of two of Plaintiffs' four asserted patents—U.S. Patent Nos. 10,689,699 (“the ‘699 patent”) and 10,752,951 (“the ‘951 patent”).

The ‘699 patent is directed to methods for analyzing circulating DNA. D.I. 1, Ex. B. The ‘699 patent issued from U.S. Patent Application No. 16/411,066 (“the ‘066 application”). *Id.* The ‘951 patent claims methods of generating high-accuracy sequence reads of a population of double-stranded target nucleic acid molecules. D.I. 1, Ex. C. The ‘951 patent issued from U.S. Patent Application No. 16/514,931 (“the ‘931 application”). *Id.* As Guardian alleges in its counterclaims, both the ‘699 and ‘951 patents claim priority to the same provisional application, filed March 12, 2012, before the effective date of the America Invents Act (AIA). *See* D.I. 30, ¶¶ 248, 274. Among other changes, the AIA changed the U.S. Patent system from a first-to-invent system to a first-inventor-to-file system. *See, e.g., Storer v. Clark*, 860 F.3d 1340, 1342 (Fed. Cir. 2017) (“the America Invents Act, the statute that abolished the first-to-invent...rule in favor of a first-to-file rule”). One consequence of this change is that pre-AIA inventors can be entitled to a priority date occurring before the effective date, whereas AIA patent filings are entitled only to the effective filing of the application. *See, e.g., Helsinn Healthcare S.A. v. Dr. Reddy's Lab. Ltd.*, 387 F. Supp. 3d 439, 490 (D.N.J. 2016) (stating AIA “redefines the effective filing date as the date of the patent application, rather than the date of the invention.” (citing 35 U.S.C. § 100(i)(1)(A)), *rev'd on other grounds*, *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 855 F.3d 1356 (Fed. Cir. 2017)).

Against each of these patents, Guardian brings two counterclaims. Counts V & VI respectively seek declarations of “unpatentability” for the two patents because Guardian alleges neither patent “name[s] the actual inventor of the claimed subject matter.” D.I. 30, ¶¶ 228, 238.

Guardant’s Fourth and Twelfth Affirmative Defenses correspond to the inventorship allegations in Counts V & VI. *Id.* at 19, 21. Similarly, Counts VII & VIII and Guardant’s Eighth Affirmative Defense seek declarations that the two patents are unenforceable due to alleged misrepresentations and omissions made to the Patent Office during prosecution of the two patents. The same basic premise underlies all four counts and related affirmative defenses: Guardant alleges that (i) Plaintiffs copied into their own patent applications claim language from a Guardant patent and a Guardant patent application, and (ii) Plaintiffs did not inform the Patent Office that they had copied Guardant’s patent claims into Plaintiffs’ patent applications. *See, e.g.*, D.I. 30, ¶¶ 140–147, 234, 242, 261, 286.

As shown below, Guardant’s counterclaims are supported by a striking dearth of *factual* allegations that do not state claims upon which relief may be granted.

IV. ARGUMENT

To survive a Rule 12(b)(6) motion to dismiss, Guardant must plead facts that, if true, are sufficient to allow “the court to draw the reasonable inference” that Plaintiffs are liable for the alleged misconduct. *See Ashcroft v. Iqbal*, 556 U.S. 662, 677–78 (2009) (citing *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007)). Rule 9(b) applies to Guardant’s inequitable-conduct counts, so they must be pled with particularity. *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326–27 (Fed. Cir. 2009). Inequitable conduct requires both materiality and an intent to deceive the Patent Office. *Therasense, Inc. v. Becton, Dickinson and Co.*, 649 F.3d 1276, 1287 (Fed. Cir. 2011) (*en banc*).

Guardant’s counterclaims V–VIII fail these standards, relying principally on “‘naked assertion[s]’ devoid of ‘further factual enhancement’” to allege that UW’s ’699 and ’591 patents are unpatentable and unenforceable due to improper inventorship and inequitable conduct. *See id.*; D.I. 30 (Counts V–VIII). Guardant’s counterclaims V–VIII and related affirmative defenses

should be dismissed, as discussed below.

A. The Court should dismiss Guardant’s inequitable-conduct challenges because Guardant has not pled sufficient, particularized facts to support them.

The Court should dismiss Guardant’s twin inequitable-conduct counts (Counts VII and VIII) and Eighth Affirmative Defense because Guardant has failed to plead particularized facts required under Rule 9(b). *See Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1326 (Fed. Cir. 2009) (“[I]nequitable conduct...must be pled with particularity’ under Rule 9(b).” (internal citation omitted)); *Evonik Degussa GmbH v. Materia Inc.*, C.A. No. 09-cv-636 (NLH-JS), 2012 WL 4503771, at *3 (D. Del. Oct. 1, 2012).

Inequitable conduct is subject to a higher pleading standard to protect the reputations of individuals from baseless allegations and frivolous litigation. *See Exergen*, 575 F.3d at 1331 (citing *FMC Corp. v. Manitowoc Co., Inc.*, 835 F.2d 1411, 1415 (Fed. Cir. 1987) and *Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1418 (3d Cir. 1997) (Alito, J.) (“To allow plaintiffs and their attorneys to subject companies to wasteful litigation based on the detection of a few negligently made errors found subsequent to a drop in stock price would be contrary to the goals of Rule 9(b), which include the deterrence of frivolous litigation based on accusations that could hurt the reputations of those being attacked.”)).

“The substantive elements of inequitable conduct are: (1) an individual associated with the filing and prosecution of a patent application made an affirmative misrepresentation of a material fact, failed to disclose material information, or submitted false material information; and (2) the individual did so with a specific intent to deceive the PTO.” *Exergen*, 575 F.3d at 1327, n.3. It is not enough for a challenger to plead the ultimate element of inequitable conduct; instead, the inquiry focus on the facts that are plead, “lest inequitable conduct devolve into ‘a magic incantation to be asserted against every patentee’ and its ‘allegation established upon a

mere showing that art or information having some degree of materiality was not disclosed.””

Exergen, 575 F.3d at 1331.

For specific intent, the complaint must allege that “a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO” such that the facts “give rise to a strong inference of fraudulent intent.” *Exergen*, 575 F.3d at 1327–29, n.4 (citing *Lerner v. Fleet Bank, N.A.*, 459 F.3d 273, 290 (2d Cir. 2006)); *see also Evonik*, 2012 WL 4503771, at *4. “In a case involving nondisclosure of information,” the allegations must indicate that “the applicant *made a deliberate decision* to withhold a *known* material reference.” *Therasense*, at 349 F.3d at 1290 (emphasis in original). A court may not infer intent solely from materiality. *Id.* (quoting *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1181 (Fed. Cir. 1995)).

Likewise, “the materiality required to establish inequitable conduct is but-for materiality.” *Therasense*, 649 F.3d at 1291. An omission or failure to disclose is “but-for” material “if the PTO would not have allowed a claim had it been aware of the undisclosed” information. *Id.*; *see also id.* at 1292–93. However, information is not material when it is “cumulative of information already of record or being made of record.” 37 C.F.R. § 1.56(b). In rare instances, “affirmative acts of egregious misconduct”—rather than omissions—may provide for an exception to the but-for materiality rule such that materiality is presumed. *See id.* at 1292. For that exception to apply, “the patentee [must have] engaged in affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit.” *Id.* In other words, an “affirmative act of egregious misconduct” is *per se* material. *See Outside the Box Innovations, LLC v. Travel Caddy, Inc.*, 695 F.3d 1285, 1294 (Fed. Cir. 2012) (citing *Therasense*, 649 F.3d at 1292)); *see also UUSI, LLC v. United States*, 133 Fed. Cl. 263, 270 (Fed. Cl. 2017).

“Just as a claim for inequitable conduct must meet the heightened pleading requirements of Rule 9(b), a defendant is also ‘required to plead this affirmative defense with particularity under Rule 9(b).’” *Senju Pharm. Co., Ltd. v. Apotex, Inc.*, 921 F. Supp. 2d 297, 306 (D. Del. 2013) (quoting *Bayer CropScience*, C.A. No. 10-1045, 2011 WL 6934557, at *3 (D. Del. Dec. 30, 2011)). Because Guardant’s Eighth Affirmative Defense pleads no facts, it must rise and fall with Guardant’s inequitable-conduct counterclaims. *Id.* (citing *XpertUniverse, Inc. v. Cisco Sys. Inc.*, 686 F. Supp. 2d 376, 379–83 (D. Del. 2012)).

1. Guardant pleads almost no facts beyond Plaintiffs’ alleged failure to notify the Patent Office of its alleged claim copying.

Guardant’s inequitable-conduct theories are premised on the underlying allegation that Plaintiffs copied patent claims from Guardant and did not inform the Patent Office that it had done so. Guardant’s inequitable-conduct claims set forth precious few *factual* allegations that are exhaustively summarized below.

Specifically, Guardant alleges the named inventors and prosecuting attorney made “misrepresentations and omissions” to the Patent Office in prosecuting the applications to the ’699 and ’951 patents, but Guardant does not allege any *misrepresentation*, just a single alleged omission in each inequitable-conduct count:

- More than one year after Guardant’s ’822 patent issued, Plaintiffs exactly⁵ copied patent claims from the ’822 patent into the application that issued as the ’699 patent, D.I. 30, ¶¶ 246, 250;
- More than one year after Guardant’s ’427 application published, Plaintiffs filed “almost exact” copies of those claims into the patent application that

⁵ As shown below, there was no exact copying of claims in the application to the ’699 patent. Section IV.A.2 *infra*.

issued as the '951 patent, *Id.*, ¶¶ 272, 274–75;

- Plaintiffs did not notify the Examiner of these alleged acts of copying, *Id.*, ¶¶ 247, 273; and
- In the case of the '699 patent, Plaintiffs nevertheless cited the '822 patent in an Information Disclosure Statement filed with the Patent Office. *Id.*, ¶ 252.

Guardant then attempts to allege that each omission was material, but it manages only to plead the ultimate issue on the question of materiality:

- Plaintiffs' failure to inform the Examiner of the alleged claim copying was material (i) "because failure to identify such information to the PTO is *per se* material to patentability," and (ii) "would have triggered an interference, [and] a much more thorough and in-depth examination." *Id.*, ¶¶ 261–62, 286–87; and
- "On information and belief," the '699 and '951 patents would not have issued if the Patent Office had been informed of the alleged copying. *Id.*, ¶¶ 263, 288.

Finally, Guardant attempts to plead that the inventors and prosecuting attorney specifically intended to deceive the Patent Office, but it only alleges that the relevant people were experienced with prosecution and knew they had a duty to disclose claim copying to the Patent Office:

- The inventors and the prosecuting attorney were "experienced before the PTO," because the prosecuting attorney has been a licensed patent attorney for more than a decade and the inventors are named on "multiple

patents and applications,” *Id.*, ¶¶ 253, 278; and

- The inventors and prosecuting attorney knew of their duty to inform the Examiner of the alleged claim copying because they had done in so in another instance, *Id.*, ¶¶ 266–69, 291–94.

Beyond that, Guardant’s inequitable-conduct counts set forth statements of law and close with examples where Plaintiffs’ inventors allegedly copied claims from other patent applications (unrelated to this litigation) into their own applications, while simultaneously citing the very same patent applications from which they allegedly copied to the Patent Office in an IDS. *Id.*, ¶¶ 265, 290.

2. Guardant does not plead adequate facts to show any individual specifically intended to deceive the Patent Office.

Guardant’s inequitable-conduct pleading does not set forth facts that would give rise to an inference of fraudulent intent, let alone a “strong inference of fraudulent intent.” *Exergen*, 575 F.3d at 1327, n.4 (citing *Lerner v. Fleet Bank, N.A.*, 459 F.3d 273, 290 (2d Cir. 2006) (emphasis added)). On the intent element, Guardant’s factual allegations are especially thin.

At most, Guardant alleges facts that might support an inference that the inventors and the prosecutor knew they had a duty to inform the Patent Office of any alleged claim copying. D.I. 30, ¶¶ 253, 266–69, 278, 291–94 (alleging individuals were “experienced before the PTO” and had notified the Patent Office of claim copying in one instance). But basic knowledge of one’s legal duty to the Patent Office is not enough to establish specific intent. *See Therasense*, 649 F.3d at 1290 (“In a case involving nondisclosure of information, clear and convincing evidence must show that the applicant made a deliberate decision to withhold a known material reference.”); *Exergen*. 575 F.3d at 1330 (“The pleading, however, provides no factual basis to infer that any specific individual, who owed a duty of disclosure in prosecuting the ’685 patent,

knew of the specific information in the '808 and '998 patents that is alleged to be material to the claims of the '685 patent.”). Were that the case, every licensed patent practitioner who failed to cite a relevant prior-art reference could be charged with a specific intent to deceive the Patent Office simply because practitioners are aware of their duty to disclose.

Likewise, Guardant’s allegation in Count VII (which it omits from Count VIII) that Plaintiffs filed *exact* copies of Guardant’s '822 patent should be given no weight because that allegation is unquestionably false. A simple comparison of the claims that Guardant alleges Plaintiffs copied into the application to the '699 patent with the '822 patent shows there are several differences. For example, the application to the '699 patent recited “circulating DNA” and Guardant’s patent does not; it recites “cell free DNA (‘cfDNA’).” *Compare* Ex. AA (independent claim 37, '066 application), *with* Ex. BB (claim 1, '822 patent).

And, even accepting as true the allegation that Plaintiffs’ copied claims were substantially similar, but not exact, to Guardant’s claims, that also fails to create a strong inference of specific intent to deceive. Guardant’s allegations of inexact copying cannot create a strong inference of intent to deceive because that simply suggests that Plaintiffs’ inventors and prosecuting attorney either (1) did not appreciate that the claims were substantially similar or (2) they reasonably believed the claims were not substantially similar. Either way, there would not be any specific intent to deceive.

Moreover, Guardant’s allegation that the relevant individuals knew of the Guardant patent and patent application when the alleged copying occurred is unavailing. In the case of the '699 patent (Count VII), Guardant alleges that Plaintiffs cited the '822 patent to the Patent Office in an IDS. D.I. 30, ¶ 252. That fact alone defeats any inference (let alone a strong one) that the relevant individuals intended to deceive the Patent Office. Would a plagiarist (as Guardant would

frame it), hoping to hide their copying, cite the copied source material in an endnote? Likewise with the '951 patent (Count VIII), Guardant's allegation that the inventors (but not the prosecuting attorney) were aware of the Guardant patent application (D.I. 30, ¶ 277) also is not enough. Under *Exergen*, Guardant must plead that a specific individual was not just aware of the Guardant application but also knew of the specific claims and that they were substantially copied—"one cannot assume that an individual, who generally knew that reference existed, also knew of the specific material *information* contained in that reference." *Exergen*, 575 F.3d at 1330. Guardant has not pled such facts.

Lastly, Guardant's allegation that Plaintiffs on one occasion copied claims in the '305 application and *notified* the Patent Office is self-defeating for two reasons. First, that allegation, if anything, shows that the inventors and prosecuting attorney acted consistent with their duty of candor to the Patent Office when they believed it was appropriate. Second, to the extent Guardant relies on these allegations to show that Plaintiffs were incentivized to withhold information from the Patent Office because "no patent issued" after "notifying the PTO of claim copying" (D.I. 30, ¶¶ 267, 268, 292, 293), Guardant's allegations fail to raise an inference of specific intent to deceive. A general desire to acquire patent rights does not amount to specific intent to deceive the Patent Office. *Invista North America S.a.r.l. v. M&G USA Corp.*, C.A. No. 11-1007-SLR-CJB, 2013 WL 12304544 (D. Del. May 3, 2013). And in any event, the application issued as U.S. Patent No. 11,242,562. Ex. CC. Not only that, given the '305 application has issued as a patent, there is no reason whatsoever to infer that Plaintiffs intended to avoid anything by allegedly not informing the Patent Office of claim copying.

The Court should dismiss the inequitable-conduct counterclaims and defense for the independent reason that Guardant has not pled sufficient facts on the specific-intent element.

3. **Guardant fails to adequately plead materiality.**

Guardant’s counterclaims also fail to plead facts explaining why the allegedly withheld information is material or how the Examiner would have used the information in assessing the patentability of UW’s claims. *See Exergen*, 575 F.3d at 1329–30. Guardant generally alleges “on information and belief” that the “failure to notify the PTO of the copied claims...is per se material to patentability” and would have triggered an interference. D.I. 30, ¶¶ 261–263, 286–288. But Guardant’s counterclaims are not supported by any facts and Guardant offers no explanation of materiality. *See Exergen*, 575 F.3d at 1330 (“Pleading on ‘information and belief’ is permitted under Rule 9(b)...only if the pleading sets forth the specific facts upon which the belief is reasonably based.”).

Instead, Guardant insufficiently recites regulations and the Manual of Patent Examining Procedure (MPEP) to plead “per se” materiality without factual support. *See, e.g.*, D.I. 30, ¶¶ 283–84; *Bot M8 LLC v. Sony Corp. of America*, 4 F.4th 1342, 1352–53 (Fed. Cir. 2021) (“[A] plaintiff’s obligation to provide the ‘grounds’ of his ‘entitle[ment] to relief’ requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” (quoting *Twombly*, 550 U.S. at 555)). To successfully plead *per se* materiality, Guardant must plead facts giving rise to a reasonable inference that Plaintiffs committed “affirmative acts of egregious misconduct.” *See Therasense*, 649 F.3d at 1292. But Guardant merely alleges that Plaintiffs “did not notify the PTO” that claims were copied. *See, e.g.*, D.I. ¶ 257. Guardant’s allegation amounts to an allegation of omission—not an affirmative, egregious act—and hardly satisfies an allegation of *per se* materiality.

Inequitable conduct allegations based on omissions require a pleading of “but-for” materiality. *See Therasense*, 649 F.3d at 1292–93 (describing allegations of “mere nondisclosure” and “failure to mention” information to the Patent Office as requiring but-for

materiality); *Evonik*, 2012 WL 4503771, at *5 (same). Guardant must therefore have pled facts leading to a plausible inference that the “PTO would not have allowed a claim had it been aware of the undisclosed” copied claims. *See Therasense*, 649 F.3d at 1291; *see also Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V.*, 528 F.3d 1365, 1375 n.3 (Fed. Cir. 2008) (noting that not all omissions are material). At best, Guardant alleges that disclosure of the allegedly copied claims “would have triggered an interference” and UW’s patents “would not have issued.” *E.g.*, D.I. 30, ¶¶ 262–63. But Guardant does not plead facts plausibly explaining why an interference would have been triggered or how and why an examiner would have used the undisclosed information to reject UW’s claims. *See Exergen*, 575 F.3d at 1327 (“in pleading inequitable conduct in patent cases, Rule 9(b) requires identification of the specific who, what, when, where, and how of the material misrepresentation or omission”).

For starters, Guardant does not allege facts suggesting why the ’699 and ’951 patents, which admittedly claim priority before the effective date of the AIA, would lose in a priority contest to Guardant’s post-AIA filings. Rather, Guardant offers pure speculation that had Plaintiffs notified the Patent Office about the alleged claim copying, the Director would have declared an interference, that the Patent Office would not terminate the interference, and that Guardant would have prevailed in any interference. *See also Bot M8*, 4 F.4th at 1353 (“[f]actual allegations must be enough to raise a right to relief above the speculative level”). Guardant’s allegations do not meet Rule 9(b) pleading standards and should be dismissed.

Lastly, Guardant fails to contend with the incontrovertible facts the allegedly copied claims changed before they issued. *See generally*, D.I. 30, ¶¶ 270–294. And Guardant’s allegation that the ’822 patent was cited in an IDS also shows that the alleged failure to notify the Patent Office of copying was immaterial and duplicative because the Examiner was already

aware of the '822 patent.

The Court should dismiss Guardant's inequitable-conduct claims and defense for the independent reason that it has not sufficiently plead materiality.

B. The Court should dismiss Guardant's inventorship challenges.

Guardant's counterclaims V and VI and Fourth and Twelfth Affirmative Defenses⁶ seek declarations that the '699 and '951 patents are "unpatentable" for failing "to name the actual inventor of the claimed subject matter." D.I. 30, ¶¶ 228, 238. To support these accusations, Guardant alleges the following facts:

- Plaintiffs "substantially copied" patent claims from Guardant's '822 patent into the application that issued as the '699 patent, D.I. 30, ¶ 141;
- Plaintiffs' alleged copying of the '822 patent claims occurred more than one year after the '822 patent issued, *Id.*, ¶ 144;
- Plaintiffs copied patent claims from a Guardant patent application into the patent application that issued as the '951 patent, *Id.*, ¶ 145;
- Plaintiffs did not notify the Examiner of either alleged act of copying, *Id.*, ¶¶ 143, 147; and
- The named inventors of the Guardant patent and patent application are not named on the '699 and '951 patent. *See id.*, ¶ 142, 146.

Beyond these facts, Guardant alleges no more than principles of law and ultimate legal conclusions. *See Xilinx, Inc. v. Invention Inv. Fund ILP*, C.A. No. 11-0671 SI, 2011 WL

⁶ Guardant's Fourth Affirmative Defense alleges that all four of Plaintiffs' asserted patents are invalid under 35 U.S.C. § 116 "for failure to name the correct inventors" and its Twelfth Affirmative Defense alleges the '699 patent is invalid for failure to comply with 35 U.S.C. § 135, which is directed to the triggering of interferences. *See D.I. 30* at 19, 21.

3206686, at *6 (N.D. Cal. July 27, 2011) (“simply ‘pleading the citation’ to a section of the Patent Act is not sufficient”). In particular, Guardant recites a provision of the MPEP (D.I. 30, ¶¶ 256, 259, 281) and quotes various parts of the patent statute (*id.*, ¶¶ 230–32, 240–41). Guardant then concludes that (i) the ’699 and ’951 patents fail to name the actual inventor (*id.*, ¶¶ 228, 238) and (ii) the patents fail to meet the requirements of the quoted parts of statute (*id.*, ¶¶ 233–34, 242).

1. Guardant has not alleged facts sufficient to show the ’699 and ’951 patents improperly name inventors.

Although Guardant cites various statutory provisions for its inventorship counts (V & VI) and affirmative defense, the crux of those counts is a derivation theory and an improper inventor theory: according to Guardant, the named inventors of the ’699 and ’951 patents did not conceive of the claimed inventions but simply copied them from Guardant’s patent and patent application, resulting in a non-joinder of the Guardant inventors and a misjoinder of the Plaintiffs’ named inventors. *See* D.I. 30, ¶¶ 228, 231, 238, 241.

Invalidity challenges based on inventorship can take several forms. Guardant appears to advance a theory of derivation and a theory of improper inventorship. To state a claim of derivation, the challenging party must (i) show that another person conceived of the claimed inventions before the named inventors and (ii) that conception was communicated to the patentee. *Cumberland Pharm. Inc. v. Mylan Institutional LLC*, 846 F.3d. 1213, 1217–18 (Fed. Cir. 2017). Insofar as Guardant’s inventorship theory is not based on derivation, but is a basic theory of improper inventorship, it still must allege facts that show the ’699 and ’951 patents name as inventors more or fewer people than the true inventors. *Gemstar-TV Guide Int’l, Inc. Int’l Trade Comm’n*, 383 F.3d 1352, 1381 (Fed. Cir. 2004).

Guardant’s Counts V & VI fail to meet either of these standards for the basic reason that

they do not allege any fact about conception. Guardant does not allege when (or even that) the named Guardant inventors conceived of the inventions that it alleges were copied into the '699 and '951 patents. Instead, it alleges that one inventor was "named" on Guardant's patent and two were named on its application. D.I. 30, ¶¶ 142, 145, 146. Likewise, Guardant does not allege any facts that any of the named inventors on Plaintiffs' applications, the '066 and '931 applications, failed to conceive of any part of the claims that issued in those patents.

Instead, Guardant's inventorship claims rest on the singular fact that Plaintiffs allegedly copied Guardant's claims. But that is not enough. Accepting as true that any claims were copied—which they were not—there is nothing improper in that practice. It is permissible in prosecuting patents before the Patent Office, as indicated by statute and regulations. *See* 35 U.S.C. § 135, 37 C.F.R. 1.607(6)(c); MPEP § 2306.01; *see also In re Spina*, 975 F.2d 854, 855, 857 (Fed. Cir. 1992) ("The description requirement of 35 U.S.C. § 112 is the same for a claim copied for purposes of instituting an interference."); *Agilent Tech., Inc. v. Affymetrix, Inc.*, 567 F.3d 1366, 1368–69 (Fed. Cir. 2009); *Johns Hopkins Univ. v. 454 Life Sciences Corp.*, 123 F. Supp. 3d 563, 566 (D. Del. 2015).

At best, Guardant's counterclaims and affirmative defenses merely recite some of the elements of a claim of improper inventorship. Guardant alleges that the '699 and '951 patents "fail[] to name the actual inventor of the claimed subject matter" because, "to the extent [these patents] claim[] inventive subject matter, such invention was not made by the named inventors." D.I. 30, ¶¶ 228, 233, 238, 242. But these allegations are "devoid of any factual allegations" and are insufficient to satisfy the pleading standards set forth in *Twombly* and *Iqbal*. *EMC Corp. v. Zerto, Inc.*, C.A. No. 12-956-GMS, 2014 WL 3809365, at *2 (D. Del. July 31, 2014).

2. Pre-AIA Section 135(b) does not provide a cause of action.

Guardant's inventorship Count V and Twelfth Affirmative Defense include an allegation

that Plaintiffs' alleged copying occurred after the period allowed by pre-AIA 35 U.S.C. § 135(b).⁷ D.I. 30, ¶ 234. But even if that allegation were true (it is not), this motion should not be denied. Section 135, by its own terms does not provide a basis for invalidity, nor is it an enumerated invalidity defense under 35 U.S.C. § 282. Underscoring this fact, no court has ruled that § 135(b) provides a private cause of action or defense of any sort in an infringement suit. Instead, § 135 "is a procedural bar to interference proceedings, not a substantive basis upon which to declare the claims of a patent invalid." *Chiron Corp. v. Genentech, Inc.*, 268 F. Supp. 2d 1148, 1171 (E.D. Cal. 2002).

Given these pleading deficiencies, the Court should dismiss Guardant's Counts V & VI and Twelfth Affirmative Defense.

C. If Counts V–VIII are dismissed, UW should be dismissed as a Counterclaim Defendant.

Should the Court grant Plaintiffs' motion to dismiss Counts V–VIII, UW requests that it be dismissed as a Counterclaim Defendant. Guardant's Counts V–VIII implicate UW's alleged acts, but Counts I–IV do not. Rather, Counts I–IV accuse TwinStrand, not UW, of infringement of Guardant's patents. Therefore, UW respectfully requests dismissal as a Counterclaim Defendant to the extent the Court dismisses Counts V–VIII.

V. CONCLUSION

For the foregoing reasons, Guardant's counterclaims, Counts V–VIII, and Guardant's Fourth, Eighth, and Twelfth Affirmative Defenses should be dismissed.

⁷ Guardant omits a similar allegation from Count VI with respect to the '951 patent. D.I. 30, ¶¶ 236–243.

Dated: February 11, 2022

Of Counsel:

Byron Pickard
R. Wilson Powers III, Ph.D.
Chandrika Vira
Anna G. Phillips
Matthew M. Zuziak
STERNE, KESSLER, GOLDSTEIN
& FOX, P.L.L.C.
1100 New York Avenue, NW
Washington, DC 20005
(202) 371-2600
bpickard@sternekessler.com
tpowers@sternekessler.com
cvira@sternekessler.com
aphillips@sternekessler.com
mzuziak@sternekessler.com

YOUNG CONAWAY STARGATT
& TAYLOR, LLP

/s/ Samantha G. Wilson

Adam W. Poff (No. 3990)
Samantha G. Wilson (No. 5816)
Rodney Square
1000 North King Street
Wilmington, DE 19801
(302) 571-6600
apoff@ycst.com
swilson@ycst.com

*Attorneys for Plaintiffs TwinStrand
Biosciences, Inc. and University of
Washington*

29093402.1

CERTIFICATE OF SERVICE

The undersigned hereby certifies that on February 11, 2022, a copy of the foregoing document was served on the persons listed below in the manner indicated:

BY E-MAIL

Brian A. Biggs
Erin E. Larson
DLA PIPER LLP (US)
1201 North Market Street, Suite 2100
Wilmington, DE 19801
brian.biggs@us.dlapiper.com
erin.larson@us.dlapiper.com

Mark Fowler
Susan Krumplitsch
Monica De Lazzari
DLA PIPER LLP (US)
2000 University Avenue
East Palo Alto, CA 94303
mark.fowler@us.dlapiper.com
susan.krumplitsch@us.dlapiper.com
monica.delazzari@us.dlapiper.com

Ellen Scordino
Kristin Beale
DLA PIPER LLP (US)
33 Arch Street, 26th Floor
Boston, MA 02110
ellen.scordino@us.dlapiper.com
kristin.beale@us.dlapiper.com

Michael Sitzman
DLA PIPER LLP (US)
555 Mission Street, Suite 2400
San Francisco, CA 94105
michael.sitzman@us.dlapiper.com

YOUNG CONAWAY STARGATT
& TAYLOR, LLP

/s/ Samantha G. Wilson

Adam W. Poff (No. 3990)
Samantha G. Wilson (No. 5816)
Rodney Square
1000 North King Street
Wilmington, DE 19801
(302) 571-6600
apoff@ycst.com
swilson@ycst.com

*Attorneys for Plaintiffs TwinStrand
Biosciences, Inc. and University of
Washington*